

PHYSICIAN ASSISTANT COMMITTEE

INITIAL STATEMENT OF REASONS

Hearing Date: 20 November 2003

Subject Matter of Proposed Regulations: Delegation of Services Agreement, Written Protocols, and Formulary – physical location, Citable Offenses – violation of 1399.544

Sections Affected: Adopt 1399.544. Amend 1399.571

Specific Purpose of each adoption, amendment, or repeal:

Section 1399.540 requires that a Delegation of Services Agreement be adopted by a physician assistant and his or her supervising physician. Additionally, a physician assistant and his or her supervising physician may adopt protocols as set forth in section 1399.545.

Section 3502.1 of the Business and Professions Code requires that a supervising physician who delegates the authority to issue drug orders to a physician assistant shall first prepare and adopt, or adopt, a written practice specific, formulary and protocols that specify all criteria for the use of a particular drug or device, and any contraindications for the selection.

Current laws and regulations are ambiguous to licensees and supervising physicians because they do not specify where these documents are to be maintained.

This proposal would adopt section 1399.544 which would specify that the Delegation of Services Agreement, written protocols, and formulary be maintained at all practice sites where the physician assistant practices. The proposed change would provide a clear understanding to licensees and supervising physicians about where to maintain these documents.

While investigating complaints against physician assistants, investigators will often ask to review these documents to determine if the physician assistant is complying with laws and regulations. The current laws and regulations do not state that investigators or agents of the committee may review these documents as part of the investigative process.

This proposal would require that the Delegation of Services Agreement, protocols, and formulary be made available to agents of the committee, Medical Board of California, or Osteopathic Medical Board of California.

Section 1399.571 specifies that the executive officer may issue citations for violations of specific code sections listed in section 1399.571.

This proposal would add violation of section 1399.544 to the list of citable offenses.

Failure to maintain a Delegation of Services Agreement, written protocols, and formulary constitutes violation of the Physician Assistant laws and regulations and may be grounds for disciplinary action.

However, violation of the proposed Section 1399.544 would be a minor/technical violation and not serious enough to warrant suspension, revocation, or probation of a license or civil or criminal action by the attorney general or district attorney.

Therefore, it would be appropriate to include violation of Section 1399.544 as a citable offense to ensure compliance with this proposed regulation.

Factual Basis/Rationale

Section 13499.540 of the Physician Assistant regulations states, in part, "A physician assistant may only provide those medical services which he or she is competent to perform and which are consistent with the physician assistant's education, training, and experience, and which are delegated in writing by a supervising physician who is responsible for the patients cared for by that physician assistant."

The Delegation of Services Agreement, written protocols, and formulary documents are the foundation of the physician assistant's practice. The Delegation of Services Agreement specifies the names of the supervising physicians who will supervise the physician assistant. It also specifies what type of medical services the physician assistant will perform, how they will be performed, how the patient charts will be reviewed and countersigned, and what type of medications the PA will transmit on behalf of the supervising physician. Additionally, this document describes emergency transport procedures for medical situations beyond the physician assistant's scope of practice.

Written protocols, if adopted, would describe the performance of medical tasks carried out by physician assistants on behalf of the supervising physician.

If a supervising physician delegates authority to a physician assistant to issue written drug orders, a drug formulary must be developed and adopted. This document would include a list of drugs that are appropriate for use in the type of practice engaged in by the supervising physician.

Maintaining these documents at the physician assistant's practice site would allow the physician assistant and supervising physician to readily access these documents for

reference as needed.

Additionally, current regulations do not specify where these documents should be maintained. It is implied that these documents will be at the physician assistant's work place. The proposed change would provide a clear understanding as to where to maintain these documents.

Since these documents are often reviewed by agents of the committee, Medical Board of California, or Osteopathic Medical Board of California for enforcement purposes and to ensure that physician assistants and supervising physicians are in compliance with laws and regulations this proposal would provide a clear understanding that these documents are required to be made available, if requested.

The committee's mandate is to protect the health, safety, and welfare of California consumers. Therefore, including violation of Section 1399.544 as a citable offense would assist the committee in its mandate to protect consumers.

Underlying Data

Technical, theoretical or empirical studies or reports relied upon (if any):
None

Business Impact

This regulation will not have a significant adverse economic impact on businesses because it only affects licensees. This initial determination is based on the following facts or evidence/documents/testimony: The proposed regulatory change would only apply to physician assistants.

Specific Technologies or Equipment

This regulation does not mandate the use of specific technologies or equipment.

Consideration of Alternatives

No reasonable alternative to the regulation would be either more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposed regulation.

Set forth below are the alternatives which were considered and the reasons each alternative was rejected:

- 1) Not adopt/amend regulation. This alternative was rejected because the current laws and regulations are ambiguous to physician assistants and supervising physicians because they do not specify where to maintain the Delegation of Services Agreement, written protocols, and formulary.
- 2) Adopt new regulation to clarify existing laws/regulations as to where to maintain these documents. Include violation of new regulation as citable offense.

The committee determined this is the most feasible alternative because it would clarify existing laws and regulations regarding maintenance of the Delegation of Services Agreement, written protocols, and drug formulary.

Violation of Section 1399.544 would be a minor/technical violation and it would be appropriate to include violation of this section as a citable offense.